Case Study:

Modernizing Data Access Enables Fast-Tracking of Cell Therapeutics

RESULTWORKS
An astrix Business

OVERVIEW:

The rise in new platforms and technologies is accelerating innovation in cell and gene treatments. CAR-T and TCR tailored immunotherapies, among others now in clinical trials and on the verge of commercialization, are just two high profile examples of cutting edge therapies in the news.

The size of the global cell therapy market was USD $6.11 billion in 2020 and is expected to reach USD $9.24 billion in 2028.

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New infrastructures are springing up to produce these novel therapies since many entail autologous cell transplantation, requiring aseptic manufacturing environments.

Research, testing, manufacture, and delivery of these next-generation therapies share similar characteristics which distinguish them from conventional pharmaceutical and biopharmaceutical products.

The nature of this new class of therapies requires every organization in the chain of discovery through manufacturing to document end-to-end visibility across the product supply chain, chain of custody, identity, and condition.

This case study discusses how a rapidly growing cell therapy company capitalized on ResultWorks unique expertise in chain of custody strategy, business process analysis, technology and architecture development, to help design and implement an effective framework and roadmap to accelerate solutions to the unique challenges inherent in this leading-edge approach to therapeutics.

BUSINESS CHALLENGE

A rapidly growing cell therapy company reached an inflexion point at which they realized it would be their data and automation that would ultimately drive their success. The company's senior leadership recognized that they needed to migrate from an environment in which data from disparate systems required being combined into spreadsheets for analysis and decision making.

These legacy processes were functioning as literal choke points, sapping precious time and money from otherwise aggressive timelines. Data needed to be more readily available to multiple stakeholders for it to be useful cross-functionally. To understand the situation in modern terminology, the company's data needed to adhere to FAIR (Findable, Accessible, Interoperable, Reusable) standards and principles if the pace of decision making was to accelerate to achieve the company's goals. Once FAIR principles were applied to data, the next component required the right tools in place to facilitate, and automate key aspects of, rapid and reliable product development decisions.

These critical decisions relied on access to unified data from previously siloed reservoirs so analytic functions became a key focus of enhanced capability. It was imperative to uncover new insights that could inform thoughtful decisions impacting everything from effective commercialization to enhanced patient experiences.

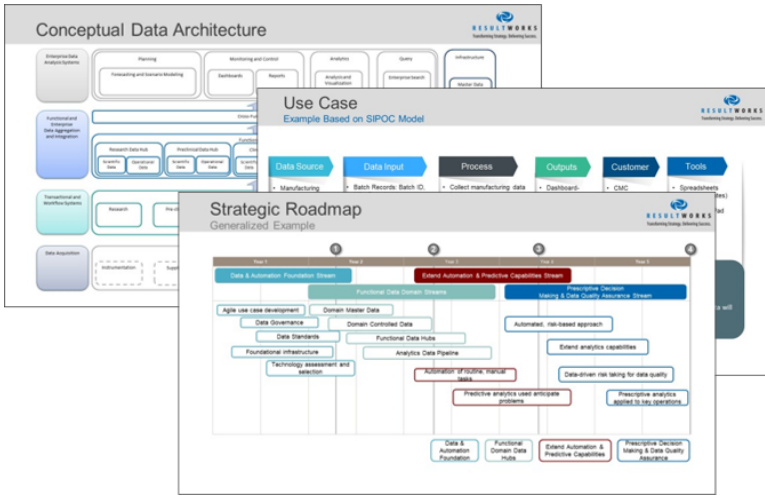## HOW RESULTWORKS ENABLED SUCCESS

ResultWorks was engaged to design and develop a data architecture for a future state that enabled the achievement of critical data-driven analysis and decisions. The program started with an assessment of data management capabilities across functional areas with particular emphasis on Research, Translational, Pre-clinical, Clinical, and Manufacturing. Each area had combinations of transactional systems and informal systems for analysis.

As part of that assessment, numerous use cases were developed to identify areas that would benefit from more accurate and accessible data, supported by appropriate analytics tools, to garner insights around patients, products, processes, and other key areas.

The assessment phase defined of technical needs organized into capabilitiy platforms, eventually leading to a conceptual technical architecture. This allowed for functional level capabilities of a broader enterprise data architecture comprised of *transactional systems and domain repositories*.

> **Since desires often outpace reality, it is important to acknowledge "where we are" versus "where we want and need to be."**

The team adapted a Data Analytics Maturity Model to baseline the organizional maturity level while showing the progression towards an aspirational ecosystem that would ultimately employ artificial intelligence with significant automation. To achieve this, the ResultWorks team managed the process of defining and creating a pragmatic, actionable, multi-year roadmap featuring step-by-step approaches for nearterm-priority projects.

To bootstrap results, the ResultWorks team conducted a rapid assessment of commercial offerings that could impact each of the key functional areas while providing value at the enterprise level.

THE RESULTWORKS IMPACT - KEY BENEFITS

Data Architecture: Developed a data architecture inclusive of research, translational, clinical, and manufacturing, depicting the data flow from collection to repositories, data structures with MDM (Master Data Management) and use of analytics for business insights.

Actionable Roadmap: Created, and enabled the client team to align on, a roadmap for the Data Architecture to be implemented with a gated, prioritized approach.

Commercial Landscape: Conducted a rapid commercial assessment to determine solutions that could readily impact the business needs.

> ResultWorks has a way of keeping us moving, keeping us focused, and delivering results.
>
> – Information Architect

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